PATENT COOPERATION TREATY

TRANSLATION INTERNATIONAL SEARCHING AUTHORITY To: WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) Applicant's or agent's file reference FOR FURTHER ACTION See paragraph 2 below YK0030 International filing date (day/month/year) Priority date (day/month/year) International application No. 13.02.2004 09.02.2005 PCT/JP2005/001902 International Patent Classification (IPC) or both national classification and IPC Applicant KABUSHIKI KAISHA YAKULT HONSHA This opinion contains indications relating to the following items: Box No. I Basis of the opinion Box No. II Priority Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Box No. III Box No. IV Lack of unity of invention Reasoned statement under Rule 43bis. 1(a)(i) with regard to novelty, inventive step or industrial Box No. V applicability; citations and explanations supporting such statement Certain documents cited Box No. VI Certain defects in the international application Box No. VII Certain observations on the international application Box No. VIII FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220. Authorized officer Name and mailing address of the ISA/JP

Telephone No.

Facsimile No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/001902

Box	No. 1 Basis of this opinion	
1.	With regard to the lunguage, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.	
	This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under	
	Rule 12.3 and 23.1(b)).	
2.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:	י
	a. type of material	
	a sequence listing	
	table(s) related to the sequence listing	١
	b. format of material	
	in written format	
	in computer readable form	
	c. time of filing/turnishing	
	contained in the international application as filed.	
	filed together with the international application in computer readable form.	
	furnished subsequently to this Authority for the purposes of search.	
	Turnished subsequently to this Addition for the purposes of seaten.	
3.	In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.	r s
4.	Additional comments:	
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/001902

Вох	No. V Reasons	ed statement under Ru s and explanations sup	c 43bis.1(a)(i) with regard to novelty, inventive step or industri porting such statement	al applicability;
1.	Statement			
	Novelty (N)	Claims	3	YES
		Claims	1, 2, 4, 5	NO NO
	Inventive step (IS)	Claims	3	YES
		Claims	1, 2, 4, 5	NO NO
	Industrial applicab	ility (IA) Claims	1-5	YES
		Claims		NO
l				

2. Citations and explanations:

Documents Cited in the ISR

Document 1: US 6653319 B1 Document 2: JP 03-004077 B Document 3: JP 2004-277374 Λ

Claims 1, 2, 4, and 5

Claims 1, 2, 4, and 5 do not appear to possess novelty or involve an inventive step. Document 1 cited in the ISR describes the use of cyclodextrin and acetic acid buffer solution in obtaining preparation of poorly water-soluble camptothecins (see example 9 in particular).

Claim 3

Claim 3 appears to possess novelty and involve an inventive step.

None of the documents 1-3 cited in the ISR describe or suggest the advantages of solubility over other acids when combining 7-ethyl-10-piperidinopiperidinocarbonyloxy camptothecin with acetic acid and sodium acetate.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/001902

В	x No. I	Basis of this opinion	
1.	With r filed, t	egard to the language, this opinion has unless otherwise indicated under this iter	been established on the basis of the international application in the language in which it was n.
			basis of a translation from the original language into the following language hich is the language of a translation furnished for the purposes of international search (under
	-	Rule 12.3 and 23.1(b)).	men is the ranguage of a translation runnished to the purposes
2.	With i	regard to any nucleotide and/or amin ion, this opinion has been established on	no acid sequence disclosed in the international application and necessary to the claimed the basis of:
İ	a. t	type of material	
		a sequence listing	
		table(s) related to the sequence list	ing _
	b . 1	format of material	
ļ		in written format	
	[in computer readable form	,
Ì	c . 1	time of filing/furnishing	·
ļ	[contained in the international appl	ication as filed.
	[filed together with the international	al application in computer readable form.
Ì	[furnished subsequently to this Aut	hority for the purposes of search.
3.		furnished, the required statements that t	one version or copy of a sequence listing and/or table(s) relating thereto has been filed or the information in the subsequent or additional copies is identical to that in the application as ion as filed, as appropriate, were furnished.
4	. Addit	tional comments:	•
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International application No.

	Lilenarion	AL SEAR	CHING AUTHORITY	PCT/JP2005/0019	UZ
Box No. V	Reasoned statemen	t under Ru nations su	ulc 43bis.1(a)(i) with regard to novel pporting such statement	ity, inventive step or industrial applicability;	
l. Statement					
Novelty	(N)	Claims	3		YE
		Claims	1, 2, 4, 5		. NO
Inventiv	e step (IS)	Claims	3		YE
					NO
			•		•
Industri	al applicability (IA)	Claims	1-5	1	YE.
		Claims			NO.
2. Citations ar	nd explanations:				
Doc Doc <u>Claims</u> Cla Doc solution	cument 1: US 6 cument 2: JP 03 cument 3: JP 20 1, 2, 4, and 5 ims 1, 2, 4, and cument 1 cited in obtaining plan).	5-00407 004-277 5 do no	7 B 374 Λ ot appear to possess nove SR describes the use of cy	lty or involve an inventive step.	-